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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/544,112

08/02/2005

Takanori Miyoshi

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SUGHRUE MION, PLLC
2100 PENNSYLVANIA AVENUE, N.W.
SUITE 800
WASHINGTON, DC 20037

EXAMINER

CHRISS, JENNIFER A

ART UNIT

PAPER NUMBER

1794

MAIL DATE

DELIVERY MODE

11/03/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/544,112	Applicant(s) MIYOSHI ET AL.	
	Examiner JENNIFER A. CHRISS	Art Unit 1794	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 19 October 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4, 6 - 8, 10 - 13 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4, 6-8 and 10 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Amendment

1. The finality of the Office Action dated June 18, 2009 is withdrawn.
2. The Applicant's Amendments and Accompanying Remarks, filed October 19, 2009, have been entered and have been carefully considered. The amendment to the Specification is entered and introduces no new matter as Applicant has shown that the Specification discusses ethylene glycol as having a molecular weight of 62 which is known in the art to be 62 g/mol. No claims are amended, claims 11 - 13 remain withdrawn and claims 1 - 4, 6 - 8 and 10 - 13 are pending. In view of Applicant's showing that the number average molecular weight is in g/mol, the Examiner withdraws the 35 USC 112, 1st paragraph rejection as detailed in paragraphs 4 – 6 of the Office Action dated June 18, 2009. However, upon further consideration of the reference cited in the previous Office Action, the invention as currently claimed is not found to be patentable for reasons herein below.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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4. Claims 1 – 4, 6 – 8 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over the Technical Paper entitled Technique Paper for Wet-Spinning Poly(L-lactic acid) and Poly(DL-lactic-co-glycolide) Monofilament Fibers".

The paper discusses wet-spinning fibers made of polylactic acid or PLGA which was dissolved in varying concentrations of solvent systems including chloroform or methyl chloride. The paper indicates that the coagulation bath included materials such as PEG 200 as well (Materials and Methods). The paper teaches that fiber mechanical and physical properties such as strength, diameter, surface tension and so on are strongly dependent on the choice of coagulation bath (Materials and Methods). The fiber diameters of 30 microns or less was easy to achieve according to the paper by choosing the appropriate spinning conditions, solvents, polymer concentrations and draw ratios (Discussion). The paper indicates in the results that they have produced fibers with diameters as small as 28 microns (Results). Additionally, the paper indicates that the fibers can be used as scaffoldings for numerous cell attachment and growth situations and indicates that the cells formed web structures between adjacent fibers (In vitro and in vivo biological results); the Examiner equates this to Applicant's "a fiber structure comprising porous fibers".

Although the paper does not specifically indicate using polylactic acid, chloroform and PEG 200 together to create a fiber, as demonstrated by the paper, all of the component parts are known and one skilled in the art could have combined the elements as claimed by known methods with no change in their respective functions. Thus, it would have been obvious to one of ordinary skill in the art at the time the

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invention was made to use create a fiber using a combination of polylactic acid, chloroform and PEG 200, since the combination of elements would have yielded the predictable result of a tailored fiber based on the desired mechanical and physical properties such as strength, diameter and surface tension for the particular end use.

The paper discloses the claimed invention except for that the average fiber diameter is 0.1 to 20 microns. It should be noted that the fiber diameter is a result effective variable. As discussed above, the fiber diameter can be controlled by using the appropriate spinning conditions, solvents, polymer concentrations, coagulation bath and draw ratios. It would have been obvious to one having ordinary skill in the art at the time the invention was made to create the fiber with a diameter of 0.1 to 20 microns since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. *In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980). In the present invention, one would have been motivated to optimize the diameter of the fiber to 0.1 to 20 microns in order to create a fiber tailored to the particular cell attachment requirements.

The paper teaches the claimed invention above but fails to teach that the fiber porosity is at least 5%. It is reasonable to presume that the porosity of at least 5% is inherent to the fiber of the paper. Support for said presumption is found in the use of like materials (i.e. a fiber made from a combination of PLA, PEG 200 and chloroform with a small diameter) which would result in the claimed property. The burden is upon the Applicant to prove otherwise. *In re Fitzgerald* 205 USPQ 594. In addition, the presently claimed properties would obviously have been present once the product of the paper is

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provided. Note *In re Best*, 195 USPQ at 433, footnote 4 (CCPA 1977). Reliance upon inherency is not improper even though the rejection is based on Section 103 instead of 102. *In re Skoner*, et al. (CCPA) 186 USPQ 80.

Applicant cannot rely upon the foreign priority papers to overcome this rejection because a translation of said papers has not been made of record in accordance with 37 CFR 1.55. See MPEP § 201.15.

Response to Arguments

5. Applicant's arguments with respect to claims 1 – 4, 6 – 8 and 10 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JENNIFER A. CHRISS whose telephone number is (571)272-7783. The examiner can normally be reached on Monday - Friday, 8:30 a.m. - 6 p.m., first Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Tarazano can be reached on 571-272-1515. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jennifer A Chriss/
Primary Examiner, Art Unit 1794

/J. A. C./
Primary Examiner, Art Unit 1794